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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/611,652	07/07/00	ZEMAN R	001290.09119

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EXAMINER	
HUI, S	
ART UNIT	**PAPER NUMBER**
1617	6

DATE MAILED: 10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/611,652	ZEMAN ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *2,3,5,8 and 10-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of the invention of Group I, claims 1-10 in Paper No. 5 filed September 10, 2001 is acknowledged. The traversal is on the ground(s) that the invention of Group I is overlapping the invention of Group II and III because they are classified in the same classes and subclasses. This is not found persuasive because the fields of search for all inventions are diverse even though the inventions are classified in the same classification. See MPEP § 808.02(c). In the instant case, it is noted that the inventions of Group I and III are independent and distinct, as the functions of the inventions are different: Group I is rehabilitating spinal cord injury and Group III is treating neurological conditions. Please note that spinal cord injury could result in conditions that are not necessarily related to neurological conditions, for example, broken bone. Neurological conditions could be Parkinson's disease or Alzheimer's disease which are not related to spinal cord injury. Therefore, the search field for rehabilitation of spinal cord injury is non-coextensive with that of treatment of neurological conditions. Furthermore, the inventions of Group I and II are related to as process of use and product. The search field for a composition containing certain ingredients is different from the search field for a particular method of use employing the same composition. The search is not limited to the patent files. Therefore, also the search for the compositions and methods claimed herein encompassed by the claims presents an undue burden to the Office.

Applicant's election with traverse of the specie of β_2 agonist, clenbuterol in Paper No. 5, filed September 10, 2001 is acknowledged. The traversal is on the ground(s)

that in US Patent 6,015,837, applicants claimed β_2-agonists as a class of agents that are similarly effective, since these are drugs designed to have the same biological effect. This is not found persuasive because firstly, patents are perceived as properties that do not constitute legal precedent. Secondly, each application for patent is examined on its own merits. The β_2-agonists recited in the claims are classified in different subclasses as stated in the previous office action mailed July 3, 2001. Therefore, the field of search for all β_2-agonists would be different. The search for all species encompassed by the claims presents an undue burden to the Office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 2, 3, 5, 8, and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

The claims have been examined to the extent they read on the elected specie.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the specification only discloses the dosage regimen from about 0.5 to about 1000.0μg/Kg/day (See specification page 9, line 1-2). The claim recites the effective dosage of clenbuterol to be 0.25 **g**/kg/day, which is equal to 250**mg**/kg/day. This dosage is 250 times higher than the highest useful dosage disclosed in the specification herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Zeman et al. (Experimental neurology 1999; 159:267-273).

Zeman et al. teaches the use of clenbuterol for treating spinal cord injury (See abstract).

Claims 1, 4, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Etlinger et al. (WO 99/09966).

Etlinger et al. teaches administration of clenbuterol in a dosage of about 0.5 to 1000.0 μg/day/kg to treat scoliosis (See page 5, line 27; page 9, line 18-19; also page 11, example 1). The instant method of rehabilitation for spinal cord injury is inherent in Etlinger et al. since this reference teaches all method steps herein. See *Ex parte Novitski* 26 USPQ 2d 1389 (BPAI, 1993).

Claims 1, 4, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Sayers et al. (Society for Neuroscience Abstracts 1998; 24: abstract 125.2).

Sayers et al. teaches the use of 1mg/kg/day of clenbuterol in treating spinal cord injury (See the last paragraph of the abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sayers et al.

Sayers et al. teaches the use of 1mg/kg/day and 10mg/kg/day of clenbuterol in treating spinal cord injury in rats (See the last paragraph of the abstract). Sayers et al also teaches that spinal cord injured animals receiving the high dose clenbuterol treatment (10mg/kg/day) have almost complete recovery (See abstract, second to last paragraph).

Sayers et al. does not expressly teach the dosage of clenbuterol is 250mg/kg/day.

It would have been obvious to one skill in the art when the invention was made to employ 250mg/kg/day in the method of rehabilitation for spinal cord injury.

One of ordinary skill in the art would have motivated to employ 250mg/kg/day in the method of rehabilitation for spinal cord injury because the effect of clenbuterol in the instant method of treatment is known and the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
October 22, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600